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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/508,765	05/13/2005	Stefan Golz	Le A 35 838 (004974.01073)	9673
22907 7590 08/01/2007 BANNER & WITCOFF, LTD. 1100 13th STREET, N.W. SUITE 1200 WASHINGTON, DC 20005-4051			EXAMINER LI, RUIXIANG	
			ART UNIT 1646	PAPER NUMBER
			MAIL DATE 08/01/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/508,765

Applicant(s)

GOLZ ET AL.

Examiner

Ruixiang Li

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3 and 26-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3 and 26-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 09/22/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group II (claims 2 and 3) and the species cardiovascular diseases in the reply filed on 06/13/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Applicants' preliminary amendments filed on 09/22/2004 and 06/13/2007 is entered. New claims 26-31 are added. Claims 2, 3, and 26-31 are pending and under consideration.

Information Disclosure Statement

3. The information disclosure statement filed on 09/22/2004 has been considered by the Examiner and a signed copy of form PTO-1449 is attached to the office action.

Drawings

4. The drawings filed on 09/22/2004 are accepted by the examiner.

Claim Rejections—35 U.S.C. § 101

5. 35 U.S.C. §101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 2, 3, and 26-31 are rejected under 35 U.S.C. §101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. A specific and substantial utility is one that is particular to the subject matter claimed and that identifies a “real world” context of use for the claimed invention which does not require further research.

Claims 2, 3, and 26-31 are drawn to a method of screening for therapeutic agent useful in the treatment of cardiovascular disease comprising determining the activity of a FPRL2 polypeptide in the presence or absence of a test compound. Since the invention is drawn to a method of screening for therapeutic agent useful in the treatment of cardiovascular disease. The determination of the utility of the claimed invention is based upon whether the agent identified by the method is useful in the treatment of cardiovascular diseases.

The specification discloses the FPRL2 polypeptide of SEQ ID NO: 2 (middle of page 4), and the distribution of FPRL2 mRNA in cells and tissues (Example 2, Table 1). The specification asserts that the invention relates to methods of screening for a therapeutic agent for the treatment of numerous diseases, including cardiovascular diseases (last paragraph of page 4). The prior art teaches FPRL2 is a chemotactic receptor transducing signals in myeloid cells (Christophe et al., J. Biol. Chem. 276:21585-21593, 2001). However, there is no evidence on the record showing that there is causative link between the FPRL2 polypeptide of SEQ ID NO: 2 and cardiovascular diseases. Clearly, further research would be required to determine whether there is a causative link between the FPRL2 polypeptide and cardiovascular

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diseases. See *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966), noting that “a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.”

Accordingly, the claimed invention is not supported by a specific and substantial asserted utility.

7. Claims 2, 3, and 26-31 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections—35 USC § 112, 2nd paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 2, 3, and 26-31 are indefinite because the steps of the methods do not necessarily achieve the goal set forth in the claim preamble. It is unclear how a therapeutic agent is selected and correlated to the preamble. It is noted that a method usually has a contacting step, a detecting step, a selecting step, and a correlation step linking the detection/selection step to the goal set forth in the preamble. In addition, the term “regulator” means either an agonist or an antagonist. It is unclear how a therapeutic agent is identified in the presence of an antagonist of FPRL2 polypeptide.

Claims 26-28 are rejected as dependent claims from claim 2, whereas claims 29-31 are rejected as dependent claim from claim 3.

10. Claims 2, 3, and 26-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 3, and 26-31 are indefinite because they recite "FRPL2". Such a term is determined arbitrarily without a definitive structure. Others in the field may isolate the same protein and give an entirely different name. Thus, reciting biochemical molecules by a particular name given to the polypeptide by various workers in the field fails to distinctly point out what the polypeptide is. Applicants should particularly point out and distinctly reciting the FRPL2 polypeptide by claiming characteristics associated with the polypeptide, such as a sequence identifier.

Claim Objections—Minor Informalities

11. Claims 2 and 3 are objected to because they recite non-elected species (diseases).

12. Claim 26 is objected to because claim 26 was canceled in the preliminary amendment filed on 09/22/2004. Thus, claim 26 needs to be numbered.

Appropriate correction is required.

Conclusion

13. No claims are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

Ruixiang Li

Ruixiang Li, Ph.D.
Primary Examiner
July 23, 2007

RUIXIANG LI, PH.D.
PRIMARY EXAMINER